

REMARKS

Claims 1-6 and 11-12 are pending in the application. Claims 7-10 have been previously cancelled.

Applicants have amended claims 11 and 12.

The rejection of claims 1-6 and 11-12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification, is traversed.

Applicants respectfully point out that contrary to the Examiner's opinion that the limitation introduced in the claim directed to "specifically producing polyunsaturated acids" has no basis or support in the present specification, it was always the intention of the Applicants to disclose a method that specifically produces polyunsaturated fatty acids as claimed and as a person skilled in the art would construe from the teaching of the description (see Examples 1 and 2 for example). It seems that the Examiner is broadening the scope of the teaching found in the description since as clearly mentioned in the section entitled "Field of the invention", the present invention relates to a new process for producing polyunsaturated fatty acid (PUFAs), and more particularly for producing omega-3, and not for producing fatty acids in general. In order to further demonstrate the specificity of the method disclosed in the present application, enclosed is a Declaration by Dr. Tremblay, one of the inventors, demonstrating that unsaturated fatty acids measured did not increase to a significant level compared to PUFAs and more specifically, to omega-3. Thus, it is believed that the Declaration enclosed herewith further demonstrate the specificity of the methodology disclosed in the present application to produce PUFAs and more specifically, omega-3. Reconsideration and withdrawal of the Examiner's rejection are earnestly solicited.

The rejection of claims 1-6 and 11-12 under 35 U.S.C. 112, second paragraph, as being indefinite is traversed.

As mentioned previously, it was always the intention of the Applicants to disclose a method that specifically produces polyunsaturated fatty acids as claimed and as a person skilled in the art would construe from the teaching of the description, in Examples 1 and 2. In view of

the argumentation presented hereinabove and the Declaration of Dr. Tremblay enclosed herewith, it is believed that the expressions “specifically producing” and “producing specifically polyunsaturated fatty acids” are clear in the context of the present application, when interpreting the claim in light of the specification. Reconsideration and withdrawal of the Examiner’s rejection are earnestly solicited.

The rejection of claims 1, 4 and 11 under 35 U.S.C. 102(b), as anticipated by McGinnis is respectfully traversed.

Applicants respectfully point out that as suggested by the Examiner, claims 11 and 12 have been amended to indicate the time at the end of the exponential phase at which the growth-limiting factor is to be applied. More specifically, claims 11 and 12 have been amended to define that the growth-limiting factor is added to the culture of diatomaceous algae at the end of the exponential growth phase after 6 to 7 days of culture, as supported in the specification at [0016]. Further, it is resubmitted that nowhere in McGinnis is there disclosed a method for specifically producing polyunsaturated fatty acids as claimed in the present application. McGinnis only teaches a method of increasing the lipid content of *C. muelleri*, without demonstrating the increase of polyunsaturated fatty acids. McGinnis specifically states that the nutrient stress is applied at day 4 (page 20, 2 para.). According to figure 3 (page 21), day four is clearly in the dormant phase of growth, not at the end of the exponential phase as stated by the Examiner in the office action. Thus, McGinnis does not teach the claimed invention, i.e., a method of specifically increasing polyunsaturated fatty acids by applying at least one growth-limiting factor to a culture of diatomaceous algae at the end of the exponential growth phase at day 6 or 7, causing growth arrest of said culture and production and stocking by said algae in culture of polyunsaturated fatty acids. Applicants wish to respectfully remind the Examiner that it is well known in the art of cell culture that the same stress applied to a cell culture at different time points on the growth curve will have dramatically different results. Applicants also respectfully remind the Examiner that demonstrating that the lipid content is increased does not necessarily mean that the polyunsaturated fatty acid content is increased. For example, the content of vitamins might increase, which will translate in an increase of the total lipids amount, without affecting the amount of polyunsaturated fatty acids. Therefore the rejection under 35 U.S .C. 102(b) for

anticipation by McGinnis is improper, especially in view of McGinnis' own admission that total lipid increases in certain diatoms but not in others (showing unpredictability), and should be withdrawn.

The rejection of claims 4, 5 and 11 under 35 U.S.C. 102(b), as anticipated by Dempster is respectfully traversed.

Applicants respectfully submit that nowhere in Dempster is there disclosed a method for producing polyunsaturated fatty acids as claimed in the present application. Dempster only teaches a method of increasing the lipid content of *N. communis*, without demonstrating the increase of polyunsaturated fatty acids specifically. Dempster teaches that, during the 10 days of culture, cells concentrations were even and did not fluctuate (around 10 millions of cells per ml). In response to this stoppage in growth, *N. communis* accumulated lipids. As pointed out above with respect to McGinnis, the nutrient stress of Dempster was applied after the exponential growth phase, during the dormant phase on Day 4 (page 19). Dempster does not teach a method for specifically increasing polyunsaturated fatty acids by applying at least one growth-limiting factor to a culture of diatomaceous algae at the end of the exponential growth phase at day 6 or 7, causing growth arrest of said culture and production and stocking by said algae in culture of polyunsaturated fatty acids. Thus, the claims are novel in view of Dempster. Therefore the rejection under 35 U.S.C. 102(b) for anticipation by Dempster is improper and should be withdrawn.

The rejection of claims 1, 3, 4 and 11 under 35 U.S.C. 102(b), as anticipated by Taguchi is respectfully traversed.

Referring to Taguchi, of record, as a whole, Applicants respectfully point out that no growth limiting factors were applied and silica deprivation should in fact be read as silica exhaustion from the media. In one embodiment of the present invention, Applicants are applying the growth-limiting factor of silica deprivation, i.e. the silica has to be removed from the media or the media changed to remove any silica therefrom. Applicants respectfully submit that nowhere in Taguchi is there disclosed a method for producing polyunsaturated fatty acids as claimed in the present application. Taguchi only teaches a method of increasing the lipid content

of *Chaetoceros gracilis*, *Hantzschia sp.* and *Cyclotella sp.*, without demonstrating the increase of polyunsaturated fatty acids specifically. Additionally, as noted above, Taguchi applies the nutrient stress during stationary phase (page 261, para. 3), and not at the end of the exponential growth phase at day 6 or 7 after culture. Figure 1 shows arrows indicating when the stress was applied, in each instance the stress was applied well into the dormant phase not at the end of the exponential growth phase, causing growth arrest of said culture and production and stocking by said algae in culture of polyunsaturated fatty acids, as claimed in the present application. Furthermore, Taguchi only teaches that, first of all, to have cell division and cell growth, it is necessary to add silica regularly to the culture, avoiding the stationary phase. On the contrary, Applicants show that positively applying a growth-limiting stress factor to the cell culture at the end of the exponential phase causes the cells to produce polyunsaturated fatty acids. Accordingly, Taguchi does not teach the steps of the claimed method. Therefore the rejection under 35 U.S.C. 102(b) for anticipation by Taguchi is improper and should be withdrawn.

The rejection of claims 1-6, and 11 under 35 U.S.C. 103(a), for obviousness are respectfully traversed.

Regarding the Examiner's rejection of claims 1-6 and 11 as allegedly obvious over McGinnis et al., taken with Dempster and Taguchi et al., Applicants reiterate that none of the references specifically teach a method for specifically increasing polyunsaturated fatty acids by applying at least one growth-limiting factor to a culture of diatomaceous algae at the end of the exponential growth phase at day 6 or 7, causing growth arrest of said culture and production and stocking by said algae in culture of polyunsaturated fatty acids. All the references cited by the Examiner are only directed to a method of producing lipids. There is no teaching or suggestion in any of the cited references that polyunsaturated fatty acids can specifically be enriched. Further, the references cited by the Examiner are not enabling for a method of specifically increasing polyunsaturated fatty acids. Applicants wish to remind the Examiner that lipids encompass a broad class of molecules such as fats, oils, waxes, cholesterol, sterols, fat-soluble vitamins (such as vitamins A, D, E and K), monoglycerides, diglycerides, phospholipids, and others. Thus, demonstrating that the lipid content is increased does not necessarily mean that the polyunsaturated fatty acids content is increased. For example, the content of vitamins might

increase, which will translate in an increase of the total lipids amount, without affecting the amount of polyunsaturated fatty acids. It is thus believed that the claims now on file are novel and inventive in view of the prior art, taken alone or combination. Therefore, the references alone and in combination do not teach or suggest the method of the instant application, nor, for the reason stated herein, do any of the references cited render the presently claimed invention obvious. Therefore, the rejection of claims 1-6, and 11 under 35 U.S.C. 103(a), for obviousness is improper and should be withdrawn.

In view of the foregoing, Applicants respectfully submit that all the pending claims should be examined and are in condition for allowance. Early and favourable action is requested.

The Commissioner is hereby authorized to charge any fees and credit any overpayments that may be due in connection with this submission to Nixon Peabody LLP Deposit Account No. 50-0850.

Respectfully Submitted,

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Enc.: -Declaration
-Petition for extension of time
-Request for Continued Examination